K070388

Attachment IV

510(k) Summary

MAY - 2 2007

Submitter:	Sciton, Inc.
Address:	925 Commercial Street, Palo Alto, CA 94303
Phone:	(650) 493-9155
Fax :	(650) 493-9146
Contact Person:	Jay M. Patel, VP of Regulatory Affairs
Date Prepared:	April 10, 2007
Device Trade Name:	Profile Multi-Platform System
Common Name:	Laser/Light Powered Surgical Device (and Accessories)
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Legally Marketed Predicate Device:	K060033: Profile Multi-Platform Laser System and Accessories K062321: Cynosure SmartLipo Nd:YAG Laser System K062822, K051287: Vascular Solutions Vari-Lase Lasers K062210, K061618: CoolTouch CTEV Nd:YAG Laser Systems K023954: Altus Medical CoolGlide Aesthetic Lasers K003715: CoolTouch Nd:YAG Laser System K050673, K043251, K033461, K033331: Candela Pulsed Dye Laser Systems K053616, K031671: Polaris WR, ST Applicator K0041242: Candela Smoothbeam Laser K051255: Opusmed LumiPhase-R K031425: Light BioScience GentleWaves LED Photomodulation Device K042165: Cutera Titan Tabletop Product K042630: RevLight Skin Care System
Description of Profile Multi-Platform System	The Profile Multi-Platform System is a modular, multi-wavelength laser/light system. The system uses scanning and focusing optics to deliver a pattern of thermal energy to the treatment site. The system consists of control console which houses the power supply, cooling system, fiber optic delivery system and/or articulated arm delivery system with handpiece and/or scanner.
Intended Use:	**1064 nm Indications for Use:** Coagulation and hemostasis of benign vascular lesions such as, but not limited to-telangiectasia and rosacea. Removal of unwanted hair, for the stable long term, or permanent hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB). The Profile 1064 Laser Systems and Accessories are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. The Profile 1064 Laser Systems and Accessories are indicated for the treatment of facial wrinkles. Incision/excision and cutting, vaporization, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. It is further indicated for laser assisted lipolysis.

1320 nm Indications for Use:

It is indicated for the treatment of fine lines and wrinkles. It is also indicated for the treatment of back acne, atrophic acne scars and mild to moderate inflammatory acne vulgaris.

Profile Multi-Platform System with fiber delivery is indicated for the treatment of reflux of great and small saphenous veins associated with varicose veins and varicosities, and for treatment of incompetence and reflux of superficial veins in the lower extremity.

2940 nm Indications for Use:

Skin resurfacing and treatment of wrinkles.

Pulsed Light (300-1400 nm) Indications for Use:

The Profile Multi-Platform Systems and Accessories are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery and dermatology.
It is intended for use for:

- The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
  (515nm LP filter, 560nm LP filter)
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
  (560nm LP filter, 590nm LP filter)
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction;
  (590nm LP filter, 640nm LP filter, 695nm LP filter)
- Treatment of facial wrinkles, treatment of fine lines and wrinkles; and
  (590nm LP filter, 640nm LP filter, 695nm LP filter, 800nm LP filter)
- Topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
  (800nm LP filter)

Technological Characteristics	The Profile Multi-Platform System shares the same indications for use, similar design features (including wavelength, laser/light medium and delivery systems, power supply, cooling and control system), functional features (including power output, repetition rate, energy, spot size and fluence), and is therefore substantially equivalent to the above legally marketed predicate devices.
Safety and Effectiveness	The indications for use are based upon the indications for use for predicate systems. Technologically, the Profile Multi-Platform System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the Profile Multi-Platform System are comparable to the predicate devices.
Conclusion	The Profile Multi-Platform System shares similar indications for use, design features, and similar functional features as, and therefore is substantially equivalent to, the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2008

Sciton, Inc
% Mr. Jay M. Patel
925 Commercial Street
Palo Alto, California 94303

Re: K070388
Trade/Device Name: Profile Multi-Platform System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 8, 2007
Received: February 13, 2007

Dear Mr. Patel:

This letter corrects our substantially equivalent letter of May 2, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

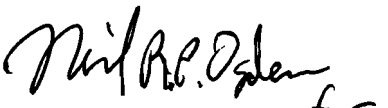
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Attachment III

Statement of Indications for Use

510(k) Number (if known): K070388

Device Name: Profile Multi-Platform System

Indications for Use:

1064 nm Indications for Use:

Coagulation and hemostasis of benign vascular lesions such as, but not limited to telangiectasia and rosacea.
Removal of unwanted hair, for the stable long term, or permanent hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB). The Profile 1064 Laser Systems and Accessories are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.
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Incision/excision and cutting, vaporization, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. It is further indicated for laser assisted lipolysis.

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2940 nm Indications for Use:

Skin resurfacing and treatment of wrinkles.

Prescription Use X OR Over-The-Counter Use _____
(Per 21CFR801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070388

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  (560nm LP filter, 590nm LP filter)
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction; and
  (590nm LP filter, 640nm LP filter, 695nm LP filter)
- Topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
  (800nm LP filter)

Mark P. Ogle for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070388